

**STATE OF MICHIGAN**  
**DEPARTMENT OF LABOR & ECONOMIC GROWTH**  
**OFFICE OF FINANCIAL AND INSURANCE REGULATION**  
**Before the Commissioner of Financial and Insurance Regulation**

In the matter of

XXXXX

Petitioner

File No. 92027-001

v

Blue Cross Blue Shield of Michigan  
Respondent

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Issued and entered  
This 6<sup>th</sup> day of October 2008  
by Ken Ross  
Commissioner

**ORDER**

**I**  
**PROCEDURAL BACKGROUND**

On August 8, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on August 15, 2008.

Because it involved medical issues the Commissioner assigned the case to an independent review organization (IRO) which provided its analysis and recommendations to the Commissioner on September 10, 2008.

**II**  
**FACTUAL BACKGROUND**

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) through the Michigan Education Special Services Association (MESSA), an underwritten group. Coverage is governed by MESSA's *Choices II Group Insurance for School Employees* certificate of coverage (the certificate).

The Petitioner suffers from back pain. She has received various forms of treatment for the condition, called lumbar spinal stenosis (a narrowing of the spinal canal that compresses or pinches nerves). The Petitioner's doctor requested pre-authorization for a surgical procedure known as X Stop Interspinous Process Decompression System (X Stop) to treat her back pain. The X Stop is a device that is inserted between vertebrae in a position that relieves pressure on the nerve canal.

BCBSM denied pre-authorization for the X Stop because it believes it to be experimental or investigational. The Petitioner appealed BCBSM's denial. After a managerial-level conference on June 11, 2008, BCBSM did not change its decision and issued a final adverse determination dated June 12, 2008.

### **III ISSUE**

Did BCBSM properly deny payment for the Petitioner's pre-authorization request for the X Stop procedure?

### **IV ANALYSIS**

#### **Petitioner's Argument**

The Petitioner is asking for approval for procedure codes 0171T and 0172T and related fees. This is known as the X Stop procedure. The Petitioner says this procedure was previously covered by BCBSM when there was no specific CPT code assigned. She says many patients had this procedure done under the generic CPT code and are very happy with the results. According to the Petitioner, costs and recovery times for this procedure are significantly lower than the alternative and the X Stop is also totally reversible.

The Petitioner has tried many conservative treatments for her back, with the exception of the X Stop procedure. She has fully investigated the pros and cons of this procedure and has concluded that this is the best option to return her to a normal life style. Her other choice is to have a laminectomy and two level lumbar spinal fusion, a much more complicated procedure with a much

longer recovery time.

The Petitioner argues that the X Stop is not investigational and is a covered benefit under her certificate. She believes that BCBSM is required to pre-authorize and pay it.

#### BCBSM's Argument

BCBSM says the X Stop procedure requested for the Petitioner is experimental or investigational and therefore not a covered benefit. It points to this provision in "Section 10: Exclusions and Limitations" of the certificate (pages 48-49):

The following exclusions and limitations apply to the MESSA Choices II program. These are in addition to limitations appearing elsewhere in the coverage booklet.

\* \* \*

- services and supplies that are not medically necessary according to accepted standards of medical practice including any services which are experimental or investigational

The certificate (page 4) defines the term "experimental or investigational" as "[a] service that has not been scientifically demonstrated to be as safe and effective for treatment of the patient's condition as conventional or standard treatment."

BCBSM's medical consultants reviewed the medical documentation and determined that the X Stop procedure is investigational because it has not been scientifically demonstrated to be as effective as conventional treatment. BCBSM notes that although results of a few studies have been promising, questions remain, including the durability of these systems. BCBSM indicates that more studies need to be completed.

BCBSM argues that the X Stop process is not a covered benefit since it is considered investigational.

#### Commissioner's Review

The certificate sets forth the benefits that are covered. A procedure that is not accepted as the standard of care and has not been demonstrated to be as safe or effective as conventional or standard treatment is considered to be experimental or investigational and is not a benefit under the

terms of the Petitioner's coverage.

The question of whether the Petitioner's proposed X Stop procedure is experimental or investigational for treatment of her condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of PRIRA. The IRO physician reviewer is board certified in neurosurgery and has been in active practice for more than ten years.

The IRO physician reviewer concluded that the X Stop procedure is investigational for treatment of the Petitioner's condition. The IRO report said:

The MAXIMUS physician consultant noted that the results of the [Petitioner's] neurological examination were normal, but that she has limited range of motion. The MAXIMUS physician consultant also noted that the [Petitioner] does not have complaints of radicular or scacroliac [*sic*] symptoms. The MAXIMUS physician consultant indicated that there is no history of neurogenic claudication. The MAXIMUS physician consultant also indicated that the radiologist's report from the MRI that [the Petitioner] underwent mentioned L4-5 changes with slight narrowing of the spinal canal. The MAXIMUS physician consultant explained that these results do not represent significant spinal stenosis.

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that the X Stop procedure is investigational for treatment of the [Petitioner's] condition.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the conclusion of the IRO that the Petitioner's proposed X Stop procedure is investigational for treatment of her condition and finds that this procedure is therefore not covered under the terms of the Petitioner's certificate.

**V  
ORDER**

Respondent BCBSM's May 14, 2008, final adverse determination is upheld. BCBSM is not required to pre-authorize or cover the Petitioner's proposed X Stop procedure since it is considered to be investigational for treatment of her condition.

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.